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AUTHORIZATION OF ACTIVITIES CARRIED OUT IN THE FIELD OF MEDICAL DEVICES

1. General and legal context

In the context of the new Covid-19 pandemic spread worldwide, the need to ensure medical equipment services is among the priorities in Romania. In this respect, on April 8, 2020, was published the Order of the Minister of Health no. 566/2020[1] ("**Order 566/2020**"), which approves the Methodological Norms for the application of Title XX of Law no. 95/2006 regarding the reform in the health system, for the authorization of activities in the field of medical devices (the "**Methodological Norms**").

Order 566/2020 was enacted by the Romanian authorities in order to adapt the current legislation to this new social and economic context, outlined by the declared state of emergency in Romania. Thus, the Methodological Norms contain derogating provisions regarding the authorization of activities in the field of medical devices in the context of such an exceptional situation, as well as additional details about the economic operators that need authorization in order to provide trading activities and services in the area of medical devices.

At last, the Methodological Norms describe in depth the authorization process and the necessary documentation that shall be submitted by the economic operators, along with details about the national authority entitled to approve and check the specific activities carried out in the field of medical devices.

[1] Order 566/2020 repeals the Order of the Minister of Health no. 1008/2016.

2. Activities and necessary requirements for the authorization

The economic operators that want to provide importing, distributing, installing and / or maintenance of medical devices must obtain an authorization in this regard, issued by the National Agency for Medicines and Medical Devices in Romania ("**NAMMDR**").

The authorization request and the necessary documentation shall be submitted to NAMMDR, for evaluation, which may last up to 120 days. The evaluation process is finalised by the issuance of an evaluation report, which may be positive or negative.

In case of a positive evaluation report, NAMMDR issues the authorization.

If the evaluation report is negative, the latter can be contested by the economic operator in front of NAMMDR. However, if the complaint is rejected, the economic operator can go further and appeal the decision of NAMMDR in front of the administrative contentious courts, possibility expressly provided by the Methodological Norms.

The validity period of the authorization is 3 years, if the conditions based on which it was issued remain unchanged. This means that the economic operators have the obligation to notify NAMMDR about any modification in their activity and the latter will re-evaluate the compliance with the legal requirements.

Because the validity period of the authorization is short, the economic operators must not wait for the expiration time to approach. If the request for renewal of the authorization, along with the documentation, is not submitted at least 6 months before its expiry date, the evaluation procedure will be resumed from the beginning.

Last but not least, it is important to note that the authorizations issued by April 8, 2020 remain valid for 2 years and a half from the date of their issuance, or for 3 years from the date of their issuance, in case the renewal request has been submitted.

3. Authority in charge

As presented above, NAMMDR is the national authority entitled to approve the activities carried out in the field of medical devices, as they are described by the Methodological Norms.

In addition, NAMMDR can carry out unannounced checks on the authorized economic operators, in order to verify the conformity of their statements with the factual situation, or whenever necessary. Because the validity of the authorizations granted has been reduced to 3 years, the said authority has no longer the obligation to carry out periodic checks.

On top of that, NAMMDR can also suspend the authorization, for a maximum period of 3 months, or it may even withdraw it, in case of non-compliance with the legal provisions in force by the economic operators.

4. The impact of the state of emergency on the authorization of activities in the field of medical devices

In order to ensure an effective legal framework in the context of unforeseen scenarios, such as the current scenario regarding the Covid-19 outbreak, the Methodological Norms contain new legal provisions regarding the establishment of the state of emergency in Romania.

Thus, for ensuring the availability of medical devices absolutely necessary in this situation, NAMMDR can issue temporary authorizations for the economic operators that provide services related to the medical devices. In this regard, the documentation to be submitted is more minimal and the evaluation procedure will be carried out under emergency conditions, within a maximum of 7 days, instead of 120 days.

However, the validity period of the temporary authorization is of only 6 months. In addition, until the expiry date and in order to keep the authorization, the economic operator must submit the other documents that were exempted in the first phase of evaluation.

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